REMARKS

Claims 68-74, 76-83, and 107-114 are pending. Claims 68, 74, and 107-113 were amended. New claim 114 was added. No new matter has been added by these amendments.

35 USC §112, second paragraph

Claims 107-133 were rejected for indefiniteness. The Examiner stated:

> Claims 107-113 are indefinite as to the phrase "wherein the composition comprising a caratenoid and a polyphenol comprises:" Applicant lists a group of ingredients, which some of them are neither a caratenoid [sp] nor a polyphenol.

Applicant believes that the Examiner is referring to claims 108-113 (rather than claims 107-113). The Examiner has acknowledged that Applicants' submission filed on October 2, 2009 was entered. The phrase "wherein the composition comprising a caratenoid [sp] and a polyphenol comprises:" is not present in claims 108-113 in Applicants' submission of October 2, 2009. The phrase was deleted in a submission made earlier (in 2007) in the prosecution history. Nevertheless, to address the Examiner's concerns and to expedite prosecution, the claims have been amended to put them into independent form. Applicants believe that the amendment is sufficient to overcome the indefiniteness rejection and therefore request withdrawal of this rejection.

35 USC §112, first paragraph

Claims 68-83 and 107-113 were rejected for lack of written description. On page 3, of the Office Action, the Examiner states:

> The claims are directed to a method of treating "a symptom of dry eye syndrome". Such method requires treatment of unspecified disease and no evidence indicates that treatable disease was known to the applicant. Therefore, the fact pattern indicates that applicant was not in possession of the claimed method of use. In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the invention.

Then on page 6 of the Office Action, the Examiner continues:

> Applicant in his remarks argues that the dry eye is a well known disorder. The examiner agrees with the applicant that dry eye is a well known disorder.

> However, the rejection was given to the phrase "a symptom of dry eye". Applicant in his remarks argues that the dry eye is associated with many symptoms, which include itching, burning, irritation, redness, blurred vision that improves with blinking, excessive tearing, increased discomfort after periods of reading, watching TV or working on a computer. The arguments have been noted. It is the examiner's position that the instant specification does not provide adequate description for using the claimed compounds or the combination of compounds for treating increased discomfort after periods of reading or watching TV, irritation, burning, itching, which can be caused by different sources different than dry eye.

The Examiner has acknowledged that Dry Eye Syndrome is a well known disorder. Dry eye syndrome is characterized by ocular inflammation. Dry eye-associated ocular inflammation manifested by several key symptoms – redness, pain, and swelling. The methods of the invention utilize a unique combination of anti-inflammatory and anti-oxidant components that surprisingly and effectively alleviate inflammatory symptoms of dry eye syndrome in human subjects. The claims have now been amended to clarify that the alleviated symptoms are symptoms of ocular inflammation associated with Dry Eye Syndrome. These symptoms ("redness, pain, and swelling") are well known in the art and clearly described in the specification, e.g., at page 2, lines 6-9 of the specification. One of skill in the art would readily recognize and understand the condition and inflammatory symptom(s) to be treated, and based on the originally-filed specification, the skilled artisan would have no difficulty accepting that Applicants were in possession of the invention as now claimed.

The written description rejection was also applied to the claim terms "carotenoid", "polyphenol", and "omega-3 fatty acid". Claim 68 has been amended to require that the carotenoid component of the OPC composition comprises astaxanthin; the polyphenol component comprises curcuma longa root powder, green tea, grape seed extract, a citrus bioflavonoid, or a cox-2 inhibitor; and the co-administered omega-3 fatty acid is either eicosapentaenoic acid or docosahexaenoic acid.

In view of these amendments, Applicants respectfully submit that the rejection for written description should be withdrawn.

35 USC §102

Claims 68, 70, 72, 73, 74, 75, 76, 77, 79, 81 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorenbein et al. (US 6,200,601). In support of this rejection for anticipation, the Examiner stated:

> Gorenbein et al. teach the use of a nutritional supplement of a fatty acid, DHA, a polyphenol and a caratenoids such as lutein and zeaxanthin for improving, delaying and preventing various vision disorders such as eye strain and night vision. See column 2, lines 1-67. The oral administration is taught in column 3, lines 1-4. The above reference makes clear that the claimed method of use is old and well known.

Independent claim 68 (from which claims 70, 72, 73, 74, 75, 76, 77, 79, 81 and 82 depend) has been amended to require that the carotenoid comprises astaxanthin. Gorenbein fails to describe astaxanthin. Therefore, this rejection should be withdrawn.

35 USC §103

Claims 68, 70, 72, 73, 74, 75, 76, 77, 79, 81, 82, 83 were rejected for obviousness over Gorenbein et al. (6,200,601) in view of Petrus (US 6,573,299). The Examiner states:

> The primary reference differs from the claimed invention in the topical administration. Petrus teaches a composition of a caratenoid [sp], a polyphenol, an oil, a lipoic acid, Vitamins, N-acetylcysteine, glutathione and minerals for ophthalmic use. See column 2, lines 20-35, column 6, lines 40-67 and column 14, lines 9-35. The topical administration is taught in column 14, lines 36-45. It would have been obvious to a person skilled in the art to use the composition of Corenbein [sp] et al. topically, motivated by Petrus reference, which teaches the use of the claimed components in an ophthalmic formulation being used topically.

As was discussed above, claim 68 was amended to require the carotenoid, astaxanthin. Gorenbein fails to describe astaxanthin. The secondary reference, Petrus also fails to describe astaxanthin. This combination of references does not describe or suggest astaxanthin. Thus, the amended claims are non-obvious over this combination of references.

Amended claims are non-obvious even in view of Petrus' description of beta-carotene, because of the unique qualities of astaxanthin. Regarding the unique and

surprising characteristics of astaxanthin, the originally-filed specification (at page 6, lines 18-23) states:

> Its molecular structure is similar to that of carotenoid beta-carotene, however small differences in structure confer large differences in the chemical and biological properties of the two molecules. In particular, astaxanthin is superior to beta-carotene in its capacity to scavenge free radicals. It exhibits strong antioxidant properties and confers protection against lipid peroxidation and oxidative damage of LDL-cholesterol, cell membranes, cells, and tissues.

The Examiner also stated:

> Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 68, 70, 72, 73, 7475, 76, 77, 79, 81, 82, 83 are properly rejected under 35 U.S.C. 103 (a).

To the contrary, data in the specification shows that astaxanthin is particularly effective in reducing expression of inflammatory markers and proinflammatory cytokines (Examples 1, 2 and Figs. 1-3 of the specification). Moreover, the prosecution history shows that Applicants have submitted evidence of surprising results in Declarations of Dr. Steven Pratt and Mr. George Ousler. Objective indicia, redness and swelling (e.g., lid edema, lid margin capping), as well as subjective indicia, pain, were evaluated in a clinical trial using the combination of ingredients of claim 68. These Declarations that were submitted to the Patent Office on November 21, 2005 establish not only the efficacy but the surprising level of reduction of patient discomfort (pain) and ocular tissue inflammation (redness/swelling) as measured by evaluation of lid edema, lid margin capping) using the claimed methods.

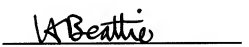
Applicants therefore submit that the amended claims are novel and non-obvious over the cited prior art.

CONCLUSION

Applicants believe that the application and claims are in condition for allowance. The Examiner is invited to contact the undersigned at the number or email listed below should she believe that there are any remaining issues that could be more easily resolved by personal or telephonic interview.

With a three-month extension of time, these documents are due on or before May 12, 2010. Applicants submit herewith a Petition for a Three-Month Extension of Time, together with an electronic payment in the amount of $555.00. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 41108-503002US (formerly: 21534-002CIP).

Respectfully submitted,



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